IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OKLAHOMA

In re: Genentech, Inc., Herceptin (Trastuzumab) Marketing and Sales Practices Litigation	)	MDL Docket No. 16-MD-2700
	)	Document Relates to:
	)	**All Cases**

DEFENDANT'S MOTION FOR ORDER REQUIRING PLAINTIFFS TO COMPLY WITH FEDERAL RULE OF CIVIL PROCEDURE 56(d) AND BRIEF IN SUPPORT

Defendant Genentech, Inc. ("Genentech") respectfully requests that this Court enter an order requiring Plaintiffs to comply with Federal Rule of Civil Procedure 56(d) to justify their requests for further discovery before responding to the obstacle preemption arguments in Genentech's summary judgment motion. Counsel for the parties have met and conferred prior to this filing and Plaintiffs object to the relief sought herein. In support of the motion, Genentech states as follows:

PRELIMINARY STATEMENT

Genentech filed its motion for summary judgment on August 23, 2016. Because Genentech's motion is based solely on federal preemption, which is a legal question requiring the Court to interpret federal statutes and regulations, the scope of applicable and proportional discovery is necessarily limited. Indeed, the only factual questions relevant to "obstacle" preemption are (1) what constitutes the federally-approved range for protein content of the drug, and (2) whether the vials Genentech sold were within the federally-approved range. Genentech has already provided Plaintiffs with more than 17,000 pages of documents in response to various requests, including the following documents necessary to address those questions:

- The Chemistry, Manufacturing and Controls section of the initial Biologics License Application (BLA) for Herceptin submitted to and approved by FDA, which contains detailed information about the manufacturing processes, formulas, FDA-approved

specifications for Herceptin, as well as responses to questions posed by FDA during its review.

- Prior Approval Supplements submitted to FDA in 2000, 2008, 2010, and 2013 seeking approval of new manufacturing sites for Herceptin drug product for distribution in the United States (as well as amendments and approval letters), which contain detailed information about the manufacturing processes for Herceptin drug product, FDA-approved specifications for Herceptin, responses to questions posed by FDA during its review, and certain correspondence with FDA.
- Each version of the final labeling (*i.e.*, prescribing information, carton label, and vial label) for Herceptin distributed in the United States.
- Documents describing the test methods and procedures for determining protein content in Herceptin vials prior to distribution.
- The Certificates of Analysis for each lot of Herceptin distributed in the United States since January 1, 2010, which show the specific protein content for each such lot.

Despite this production, Plaintiffs insist more discovery is needed before they can respond to the obstacle preemption arguments in Genentech's summary judgment motion.

In an effort to steer the parties towards resolution of the outstanding discovery issues, the Court suggested that Genentech limit its summary judgment motion to obstacle preemption and defer its arguments regarding impossibility preemption. The Court also directed Plaintiffs to assemble a list of proposed facts regarding obstacle preemption arguments that they hoped further discovery would permit them to prove. When the parties were unable to agree on a set of proposed facts Plaintiffs could submit in lieu of obtaining further discovery, the Court—recognizing that simply accepting certain things as true would unfairly handicap Genentech[1]—asked that the proposed facts be restated as "issues" and instructed the parties to continue discussions regarding the proposed issues and the process by which they would be addressed.[2] Although some progress was made with respect to the list of proposed issues,[3] the parties were ultimately unable to agree.

[1] Transcript of December 14, 2016 Hearing ("12/14/16 Hrg. Tr.") at 26:5–26:21.

[2] 12/14/16 Hrg. Tr. at 36:7–36:23, 37:9–37:11.

[3] The current list of "issues" is attached as Exhibit 1.

Throughout the meet-and-confer process, Genentech maintained that it should be able to respond to a number of the items on Plaintiffs' list of "issues." Genentech's position is consistent with statements from the Court indicating that restating proposed facts as "issues" would leave in place Genentech's ability to argue that certain things are (1) legal questions; (2) irrelevant facts; or (3) established by evidence already in the record.[4,5] While Plaintiffs acknowledge that Genentech may argue that an issue is legal rather than factual or that it is not material to the Court's determination of obstacle preemption, Plaintiffs have proposed a procedure (attached as Exhibit 2) that effectively requires Genentech to agree that all "issues" be accepted as true (*i.e.*, resolved in Plaintiffs' favor)[6], and entirely forecloses Genentech's ability to present any evidence whatsoever or argue in its reply that an issue has already been established to the contrary.[7] Indeed, Plaintiffs even proposed that Genentech should not be allowed to ask the Court to take judicial notice of any facts, *e.g.*, what was approved by the FDA. Genentech raised concerns with and invited further discussion regarding Plaintiffs' proposed procedure on January 4, 2017 (correspondence attached as Exhibit 3). Genentech further proposed that presentation of Plaintiffs' proposed issues be governed by Federal Rule of Civil

[4] *See* 12/14/16 Hrg. Tr. at 26:5–27:7.

[5] In their Status Report on Preemption Discovery (Dkt. No. 160), Plaintiffs appear to suggest that Genentech wishes to present new evidence in a reply and that would be unfair to Plaintiffs if they are denied discovery. Plaintiffs misrepresent Genentech's position. Throughout and the meet and confer process, Genentech has never suggested that it wants to present new evidence. Instead, Genentech has repeatedly said it should be able to point to evidence already in the record.

[6] "In their Response, Plaintiffs may argue that under the standard of review applicable to summary judgment motions, the Disputed Issues must be resolved in Plaintiffs' favor for purposes of the Refiled Motion. Defendant will not oppose this position [in] its Reply Brief (the 'Reply')." *See* Ex. 2 at para. 4.

[7] "In its Reply, Defendant may not argue a Disputed Issue is actually undisputed and may not introduce summary judgment evidence related to that issue or intended to show a Disputed Issue is undisputed. Defendant will not introduce any new evidence in connection with its Reply and will not ask the Court to take judicial notice of any facts." *See* Ex. 2 at para. 6.

Procedure 56(d). Plaintiffs have stated that they disagree.

The limitations set forth in Plaintiffs' proposed procedure unfairly impair Genentech's ability to support its summary judgment motion. The proposed procedure, for example, prevents Genentech from citing the previously-produced final labeling—which FDA approved and which has never expressed the concentration of reconstituted Herceptin using a decimal figure—to address Plaintiffs' proposed issue regarding whether "[t]he FDA instructed Genentech to accurately state the concentration of reconstituted Herceptin, including using a decimal for increased accuracy."[8] It also prevents Genentech from citing to previously-produced evidence of FDA's approval of Herceptin and its final labeling to address Plaintiffs' proposed issue regarding whether "[t]he FDA did not examine whether the concentration of reconstituted Herceptin as reported on the Herceptin labeling was accurate."[9] Remarkably, Plaintiffs' proposed procedure even goes so far as to prohibit Genentech from asking the Court to take judicial notice of any facts.[10]

Despite the impasse, the negotiation efforts have not been in vain. Although Plaintiffs had provided some explanation of their potential arguments in a prior joint submission, creating the list of issues has allowed the parties to more fully understand their relative positions and has narrowed the focus of the summary judgment motion to obstacle preemption. Because Plaintiffs have finally articulated exactly what discovery they believe they need before responding to the obstacle preemption arguments in the pending motion for summary judgment, Genentech submits that Rule 56(d) is the appropriate mechanism for resolving whether additional discovery

[8] Ex. 1 at No. 24.

[9] Ex. 1 at No. 18.

[10] *See* Ex. 2 at para. 6.

is necessary. Indeed, Rule 56(d) was designed for this very situation.[11] Requiring compliance with Rule 56(d) will ensure both sides can fully brief their arguments on discovery issues, and will ensure a clear record is preserved. As discussed below, the Tenth Circuit has laid out specific steps a party must follow to satisfy Rule 56(d). The Court should direct Plaintiffs to follow this procedure.

ARGUMENT

"[A] proper Rule 56(d) motion puts the district court on notice not only that there may be uncompleted discovery…but also that the movant contends the uncompleted discovery is material to the issues raised on summary judgment and warrants deferral of any disposition." *Handy v. City of Sheridan*, 636 F. App'x 728, 735 (10th Cir. 2016).

To comply with the demands of Rule 56(d), a party must identify "by affidavit or declaration": "(1) the probable facts not available, (2) why those facts cannot be presented currently, (3) what steps have been taken to obtain these facts, and (4) how additional time will enable the party to obtain those facts and rebut the motion for summary judgment." *Valley Forge Ins. Co. v. Health Care Mgmt. Partners, Ltd.,* 616 F.3d 1086, 1096 (10th Cir. 2010) (quoting *Comm. for the First Amendment v. Campbell*, 962 F.2d 1517, 1522 (10th Cir. 1992)) (internal quotations and brackets omitted); *see also Horner v. Tyson Foods, Inc.,* 2012 WL 5995966, at *2 (N.D. Okla. Nov. 30, 2012). "[M]ere assertions that discovery is incomplete or that specific facts necessary to oppose summary judgment are unavailable do not suffice." *Handy*, 636 F. App'x at 735 (quoting *Pasternak v. Lear Petroleum Expl., Inc.*, 790 F.2d 828, 833 (10th Cir.1986)) (internal quotations and brackets omitted). Thus, the Tenth Circuit requires the non-movant to show which facts are ***probable*** and ***material*** and ***currently unavailable*** to them.

[11] Plaintiffs' proposed procedure notes that Rule 56(d) "provides an alternative method to address a situation where facts are unavailable to the nonmovant." *See* Ex. 2 at para. 8(b).

Id.

Plaintiffs have identified 36[12] issues they contend are relevant to obstacle preemption, but which require further discovery to allow them to present evidence on these issues. However, Plaintiffs have not yet explained to this Court why it is ***probable*** that any evidence supporting those facts exists, why they cannot currently present those facts, the steps they have taken to obtain those facts, or how additional time will allow them to obtain those facts and rebut Genentech's summary judgment motion, *i.e.*, show how the facts are material to defeating the motion. Compliance with Rule 56(d) ensures that rulings on motions for summary judgment are not unnecessarily delayed and that any additional discovery is material to resolving the motion. Only by requiring compliance with Rule 56(d) can the Court and the parties be sure that Plaintiffs are seeking the discovery they need "in good faith" rather than simply inventing a wish list of disputed material facts in an attempt to defeat summary judgment. *Id.*

First, Plaintiffs must show that the facts they seek are "probable," not just conceivable. *Valley Forge*, 616 F.3d at 1096; *Hunnicutt v. Zeneca, Inc.*, 2012 WL 4321392, at *1 (N.D. Okla. 2012) (Kern, J.) (The party moving under Rule 56(d) must set forth a "basis for believing that specified facts, susceptible of collection within a reasonable time frame, probably exist and indicate how the emergent facts, if adduced, will influence the outcome of the pending summary judgment motion.") (citations omitted). Rule 56(d) "is not a license for a fishing expedition." *Ellis v. J.R.'s Country Stores, Inc.*, 779 F.3d 1184, 1208 (10th Cir. 2015) (quoting *Lewis v. City of Ft. Collins*, 903 F.2d 752, 758-59 (10th Cir. 1990)). If Plaintiffs "only raise a speculative hope of unearthing evidence sufficient to prevail at summary judgment," the Court should deny additional discovery. *Id.* at 1206-07; *see also Trans-Western Petroleum, Inc. v. U.S. Gypsum*

[12] From the original 40 facts Plaintiffs' proposed, the parties agreed to one and three were withdrawn by Plaintiffs.

Co., 830 F.3d 1171, 1175 (10th Cir. 2016) ("[A] party's mere hope that discovery may yield further evidence is insufficient to defeat a summary judgment motion."); *see also Horner*, 2012 WL 5995966, at *2 ("Unverified assertions in attorney memoranda are not a suitable substitute for the required affidavit. . . . Plaintiff may not benefit from the protections of Rule 56(d) without complying with the requirements of Rule 56(d)"). Plaintiffs should have to state why they believe it is ***probable*** that discovery on each of their proposed issues actually exists—especially given that a number of the proposed issues (1) relate to facts that are demonstrably false and refuted by documents already in Plaintiffs' possession,[13] or (2) speculate that Genentech may have received communications from FDA indicating that FDA had failed to consider certain things it was required to before approving Herceptin nearly two decades ago.[14]

Second, Plaintiffs need to show why they cannot currently present their proposed facts. *Wells Fargo Bank v. Lincoln Nat. Life Ins. Co.*, 2011 WL 2216689, at *4 (N.D. Okla. June 7, 2011) ("[A] party seeking to defer a decision on summary judgment must provide an affidavit identifying the facts not available [and] why those facts cannot be presented currently."). Such a showing is particularly warranted here for two reasons. First, a number of the proposed issues may be addressed by documents Plaintiffs already possess. For example, the issue of whether "Genentech targets a fill weight/volume that results in less than 440 mg of trastuzumab per vial of Herceptin" may already be addressed by produced documents reflecting the protein content of Herceptin vials distributed within the United States since 2010. Second, Plaintiffs asserted in a

[13] Plaintiffs' list of proposed issues also includes legal issues rather than material factual issues; accusations improperly suggesting fraud on the FDA, which is itself a preempted claim; and issues not material to the Court's determination of obstacle preemption.

[14] *See, e.g.*, Ex. 1 at No. 13: "FDA informed Genentech that the FDA never actually considered whether the statement on the Herceptin labeling regarding the net quantity of contents was accurate in light of the range for Herceptin strength approved in the Herceptin BLA."; and No. 14: "FDA informed Genentech that the FDA had never evaluated whether the Herceptin labeling complied with 21 C.F.R. § 201.51(g)."

filing several months ago that documents previously produced by Genentech are fatal to its preemption arguments. *See, e.g.,* Parties Joint Submission Regarding Preemption Discovery [Doc. #130] at pp. 9-10.

Third, Plaintiffs must explain the steps they have taken to obtain the information regarding the proposed issues—beyond just serving discovery requests on Genentech.

Finally, Plaintiffs must explain why each of the proposed issues on which they seek discovery relates to facts that are ***material*** and how additional time will enable them to obtain those facts and rebut Genentech's motion for summary judgment. *Handy*, 636 F. App'x at 735. Plaintiffs have not satisfied these four requirements in any court filing or appearance to date. "If a party fails to comply with this directive, 'he has waived the argument that the grant of summary judgment should be set aside for lack of sufficient discovery.'" *Id.* (quoting *Campfield v. State Farm Mut. Auto. Ins. Co.*, 532 F.3d 1111, 1124 (10th Cir. 2008)).

Pinsonneault v. St. Jude Medical illustrates how another court used Rule 56(d) to address similar preemption-related discovery issues. In that case, various disputes arose between the parties concerning the proper scope of preemption discovery. *Pinsonneault v. St. Jude Medical, Inc.*, 2014 WL 2879754, at *5 (D. Minn. June 24, 2014). The discovery disputes were similar to the ones here and

> …grew out of a disagreement about whether documents that St. Jude had not submitted to the FDA were nevertheless relevant to the issue of preemption. St. Jude argued that, for preemption purposes, the only relevant documents were documents that had actually been submitted to the FDA during the PMA process—specifically, the PMA and PMA Supplements. (St. Jude also agreed that the FDA's approval letters were relevant.) Plaintiffs sought much more than that, including a broad array of St. Jude's internal documents relating to the [medical device].

Id. at *2. The plaintiffs ultimately filed a Rule 56(d) request, which then allowed the court to evaluate the proper scope of discovery. *Id.* at *5-6. The court held that the application to FDA

and certain documents referenced in it were discoverable, but it denied that St. Jude's "purely internal" documents were necessary. *Id.* at *6-7. The court ultimately held that plaintiffs fell "far short of demonstrating that they [were] entitled to yet more discovery," *id.* at 8, deciding the summary judgment motion in the favor of the defendants.

Genentech believes that complying with Rule 56(d) will similarly narrow any remaining discovery to issues related to the obstacle preemption arguments in its summary judgment motion. It will require Plaintiffs to show—for the first time—which facts are ***probable*** and ***material***, and also ***currently unavailable*** to them. Compliance with Rule 56(d) would allow Genentech to respond appropriately to Plaintiffs' arguments, establish a clear record, and allow the Court to decide what further discovery, if any, is necessary before Plaintiffs respond to the obstacle preemption arguments in the pending summary judgment motion.

CONCLUSION

For these reasons, Genentech asks the Court to enter an order requiring Plaintiffs to comply with Federal Rule of Civil Procedure 56(d) to justify the additional discovery they seek regarding obstacle preemption.

Respectfully Submitted,

/s/ William W. O'Connor

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CERTIFICATE OF SERVICE

I hereby certify that on this 9th day of January, 2017, I electronically transmitted the foregoing document to the Clerk of the Court using the CM/ECF System for filing and distribution of the notification of such filing to all counsel of record as required in the Court's Practice and Procedure Order (MDL Doc. #6 at ¶5).

/s/ William W. O'Connor
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